



White Paper on

The pharma industry is evolving and a demand for integrated CDMOs, which can help accelerating innovations, is part of this evolution.



The major factor driving the progress of CDMOs in the pharmaceutical industry is the growing need for advanced processes and production technologies as well as the ability to rapidly adapt advanced science, which have proven highly effective in meeting regulatory and market requirements. In the last decades, we have seen a constantly increasing growth in the pharmaceutical market growth.

During 2019, the US Food and Drug Administration (FDA) approved 48 new drugs (38 New chemical entities and 10 biologics). Out of 48 approved drugs, 42% are first-in-class, 44% are rare or orphan diseases, 35% are fast track, 27% are breakthrough therapy, 58% are priority review and 19% are accelerated approval category. Overall, 60 %of the novel drug approvals of 2019 were designated in one or more expedited categories of fast track, breakthrough, priority review, and/or accelerated approval. In the last 10 years, FDA results show an increasing approval of biologics drugs (biosimilars, antibody drug conjugates, antibodies, polysaccharides, vaccines and proteins), TIDES (peptide and oligonucleotides), cell therapy, gene therapy and drug combinations. The number of biologics in the pipeline are increasingly lead to more complexity at all stages, which require advanced technology platforms and expertise, which is an increasing cost factors for pharma companies.

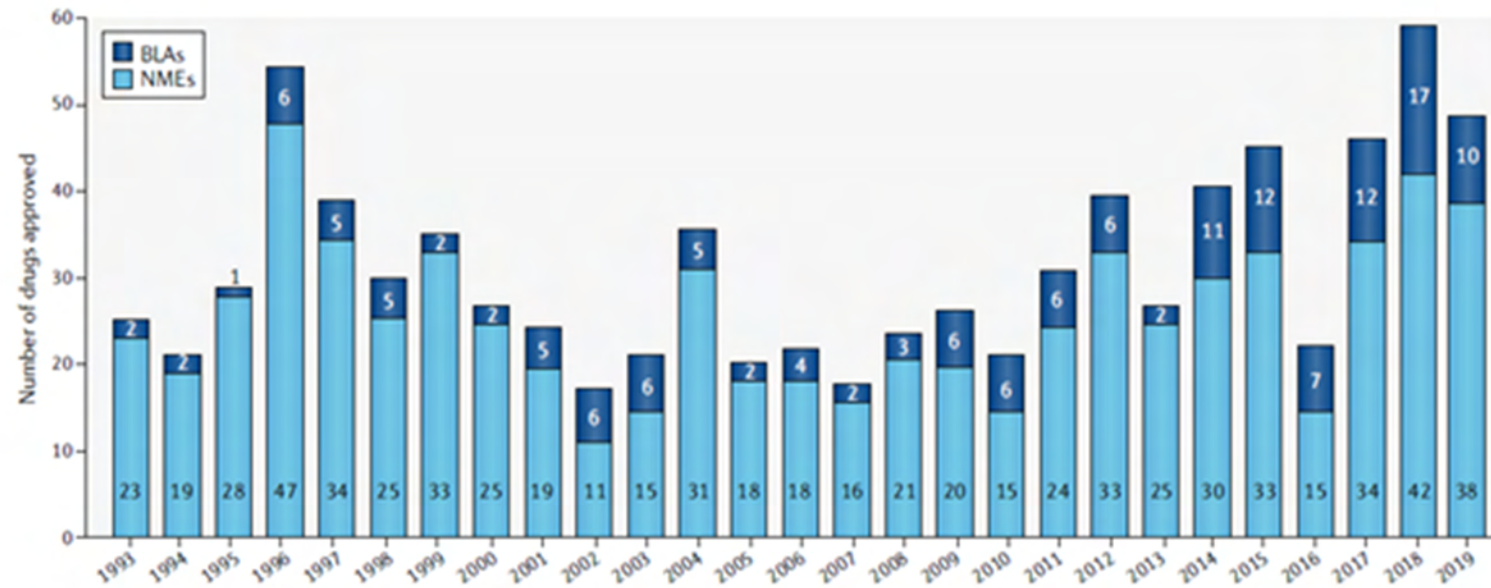


Fig. 1 | Novel FDA approvals since 1993. Annual numbers of new molecular entities (NMEs) and biologics license applications (BLAs) approved by the FDA's Center for Drug Evaluation and Research (CDER). See TABLE 1 for new approvals in 2019. Approvals of products such as vaccines and gene therapies by the Center for Biologics Evaluation and Research (CBER) are not included in this drug count (see TABLE 2). Source: Drugs@FDA.

Across the industry - from virtual biotech to large pharma – drug developers are managing R&D cost, addressing capacity constraints, and accessing innovation by outsourcing activities that were historically handled in-house. To keep pace with changing R&D needs and to ease the difficulties faced by pharma and biotech, CDMOs are now handling contracted work in various modalities, offering everything from full-time employee labor agreements to full development programs. And by utilizing these services, pharma and biotech companies can fully focus on the pipeline and the market launch of the drug.



Demands placed on CDMOs are increasing in complexity and scalability

With a wide option of service providers each handling specific activities such as discovery chemistry, preclinical toxicology, clinical research, formulation development, and manufacturing – the lack of horizontal integration has not only replicated inefficiencies in workflows and processes but has generated a siloed mindset across the drug development process.

Pharma companies are looking for new strategies to help them overcome a multitude of research challenges and achieve milestones as quickly as possible. This is where a fully integrated CDMO, such as [Aurigene Pharmaceutical Services](#), can help. By providing innovation in the service sector through smarter R&D and bringing together the offering of CDMO and CRO under one roof, significantly reduces the outsourcing complexity and accelerates the time to market for a drug. This model has broken down barriers, created an opportunity to improve efficiencies, and fostered a consistent exchange of information to the project sponsor.

Being a fully integrated CDMO, Aurigene Pharmaceutical Services can help pharma companies with the following services:

- Discovery chemistry
- Discovery biology
- Custom chemical development and manufacturing (Intermediates, APIs and drug products)
- Scalable manufacturing from clinical to commercial quantities of RSM/KSM, APIs and formulations
- CMC documentation and support for IND/NDA filings

As a long-term partner, Aurigene Pharmaceutical Services harmonizes and scales outsourcing activities along the whole value chain.

- State-of-the-art facility and ISMS certification in IT
- Robust IP protection
- Flexibility and seamless project management
- Continuous information flow and transparency
- Seamless transfer of material, process and information across the value chain
- Strong supply chain management team
- Time and cost efficiency
- Regulatory affairs support: filing INDs and NDAs with international authorities such as the US FDA, EMEA and DCGI (India).

Utilizing and leveraging strong capabilities and capacities, Aurigene Pharmaceutical Services has the expertise, technologies, and skill sets in place to address the increasing complexity in drug development and manufacturing.

- Small molecules
- High Potent APIs (HPAI)
- Peptides
- Carbohydrates
- Steroids
- m-PEG's
- Prostaglandins
- Complex intermediates
- Formulation development
- Biology services incl. bioassays, ADME/PK, in vitro and in vivo toxicology and safety studies

The one-stop-shop model of a fully integrated support at all the stages of [drug discovery](#) to commercialization of a molecule can significantly accelerate innovation to meet the demand for new medicines for patients worldwide. Aurigene Pharmaceutical Services is committed to provide high quality services to its customers and take this mutual responsibility to improve the quality of life of patients.

For more information please visit
<https://www.aurigeneservices.com/>

To place an inquiry please visit
<https://www.aurigeneservices.com/form/contact>

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Reference

1. <https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2019>

Thank You



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